

SEARCH MOP - Section 10
Extended Core
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10. Extended Core Information

10.1. OVERVIEW

In order to meet a main goal of the SEARCH study, which is the estimation of incidence of diabetes by age, sex, race/ethnicity, and diabetes type, it is critical to obtain “core” data elements for all registered cases. In SEARCH Phase 3, this data will be collected on all 2010 - 2015 incident cases. The core data includes: date of birth, sex, race/ethnicity, and (provider assigned) diabetes type.

In addition, since the inception of SEARCH Phase 2, the study has collected “extended core information” on all registered incident cases, in order to assist understanding of typology. Extended core data currently includes: autoantibody testing history, height, weight, insulin use, acanthosis, and DKA history.

10.2. SOURCES OF DATA

10.2.1. Core Information from the Tracking Database

Core data elements (date of birth, sex, race/ethnicity, and provider assigned diabetes type) should be entered into the local tracking database at the time of registration and uploaded directly to the Coordinating Center.

Note: Collection of core data may be constrained by local IRB or institutional guidelines. For example, a Data Use Agreement and/or HIPAA waiver may be required. Be familiar with your local policies prior to accessing and uploading patient information.

10.2.2. Core and Extended Core Information from Data Collection Forms

The Extended Core form and the Initial Participant Survey (IPS) both contain core and extended core information. In SEARCH Phase 3, sites should attempt to complete both of these forms on all 2010 - 2015 incident cases.

10.2.3. Quality Control and Data Analysis

If core information for a registered case is not transmitted to the Coordinating Center (CoC) via any of these sources (tracking database, Extended Core form, or IPS), the CoC will query the study center for age, sex, race/ethnicity, and/or diabetes type.

For analysis, the Coordinating Center will prioritize Core data elements according to the source of the data, searching from the highest priority source (considered most accurate) to secondary priority sources. Information from the tracking database is always the lowest priority.

10.3. EXTENDED CORE FORM COMPLETION

NOTE: Sites may begin completion of this form at diagnosis (especially to assist in validation of the case), but the form should be finalized at or after 6 months post-diagnosis to avoid missing data. It is most critical to gather diabetes type, insulin use, diabetic ketoacidosis data, and antibody testing information at and up to 6 months post-diagnosis. The Extended Core form data collected should only reflect the diagnosis date to 6 months after diagnosis, regardless of when the form is completed.

Over the course of the study, sites have found a few participants who have been diagnosed with MODY or other rare genetic diabetes types more than 6 months after diagnosis. If sites do incidentally find a change in diabetes type more than 6 months after diagnosis, then they should revise the Extended Core Form for that case to reflect the new diagnosis. The new diagnosis should be noted in question 7b, “the most recent one at 6 months”.

Given the expected small number of these cases that this impacts, sites should not make a systematic effort to go back and check all records for all cases, in order to find out if diabetes type has changed more than 6 months after diagnosis. Additionally, the template for the Extended Core Form will not be changed to reflect this procedural change. (02/2014)

This section provides instructions for filling out the questions included in the Extended Core Information Form. Potential sources for this information include the case referral source and the medical record(s). The medical record is the preferred data source. This form should *not* be completed using self-report of the study participant.

Question 1 asks for the participant’s date of birth

- Fill out as much as is available. If the specific day of birth is unknown or unavailable, enter “00” in that field.

Question 1a asks where the participant’s date of birth was obtained

- If the information was obtained from a medical record or from a provider/case source referral, check the appropriate box.
- If the information was obtained from another source, check the box labeled “Other” and specify where the source data was obtained.

Question 2 asks for the participant’s sex

- Check the box for either Female or Male.

Question 2a asks where information about the Participant’s sex was obtained

- If the information was obtained from a medical record or from a provider/case source referral, check the appropriate box.
- If the information was obtained from another source, check the box labeled “Other” and specify where the source data was obtained.

Question 3 asks for the participant's race/ethnicity

- Check the box describing the participant's race.

Note: Examples provided should not be considered to be all inclusive.

Question 3a asks where the information about the participant's race/ethnicity was obtained

- If the information was obtained from a medical record or from a provider/case source referral, check the appropriate box.
- If the information was obtained from another source, check the box labeled "Other" and specify where the source data was obtained.

Question 4 asks for the date of diabetes diagnosis

- Record the date of diabetes diagnosis. Fill out as much as is available. If the specific day of diagnosis is unknown or unavailable, enter "00" in that field.

Question 4a asks where the information about the Participant's date of diagnosis was obtained

- If the information was obtained from a medical record or from a provider/case source referral, check the appropriate box.
- If the information was obtained from another source, check the box labeled "Other" and specify where the source data was obtained.

Question 5 asks about the participant's zip code of residence at diabetes diagnosis

- Record the participant's zip code at the time of diabetes diagnosis.
- This is the zip code during the index year, i.e. the zip code that would make them eligible to be registered. So for example an incident 2010 case could be diagnosed in an ineligible zip code, and move residence to an eligible zip code within 2010. The latter zip code would be the one to enter here.

Question 5a asks where the information about the participant's zip code was obtained

- If the information was obtained from a medical record or from a provider/case source referral, check the appropriate box.
- If the information was obtained from another source, check the box labeled "Other" and specify where the source data was obtained.

Question 6 asks about the participant's county and state of residence at diabetes diagnosis

- Record the participant's county and state at the time of diabetes diagnosis.
- This is the county and state during the index year, i.e. the county and state that would make them eligible to be registered. So for example an incident 2010 case

could be diagnosed in an ineligible county and state, and move residence to an eligible county and state within 2010. The latter county and state would be the one to enter here.

Question 6a asks where the information about the participant's county and state were obtained

- If the information was obtained from a medical record or from a provider/case source referral, check the appropriate box.
- If the information was obtained from another source, check the box labeled "Other" and specify where the source data was obtained.

Question 7 asks about type of diabetes

- Check the type of diabetes noted closest to diagnosis and at 6-months post diagnosis. **If there are no visits after diagnosis, the diagnosis type at diagnosis should be entered in question 7b as well as 7a. If there were no visits other than the diagnosis visit during the 6 month period, but there was a visit after 6 months, it should NOT be entered in the 6 month field.**
- This is the type of diabetes as indicated by a clinical provider via medical records or direct referral. It is *not* the type of diabetes as determined by SEARCH laboratory work.

Note: Notations of 'hybrid' or those that may be uncertain of type, e.g., type '1.5', should be listed as "Other" specifying in the box provided, the wording noted in the source. If the type is unknown by the provider, indicate "unknown" in the "other" box.

- If diabetes type is "other", a specify box is on the form. Record the appropriate code for "other specify". See 10.4 for the list of "other specify" codes. (2/13)

Question 7a asks where the information about the participant's type of diabetes was obtained

- If the information was obtained from a medical record or from a provider/case source referral, check the appropriate box.
- If the information was obtained from another source, check the box labeled "Other" and specify where the source data was obtained.

Question 8 asks if diabetes autoantibodies were measured *at diagnosis or later (the window is from diagnosis to 6 months post diagnosis)*

- Check the appropriate box. If the answer is "Yes," complete the table requesting information about the type of antibody obtained, e.g., GAD, IA2/ICA512, ICA, IAA.

- You can mark “Yes” if the medical record notes diabetes autoantibodies were ordered. (You do not need to verify that the results are in the medical record).
- You do not need to indicate whether the testing was positive or negative.

Example

8. Were diabetes autoantibody (DAA) measures obtained at diagnosis or later? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 8a. If yes, check which measure below:				
Test (antibody):	<input type="checkbox"/> GAD/GAA obtained	<input type="checkbox"/> IA2/ICA512 obtained	<input type="checkbox"/> ICA obtained	<input type="checkbox"/> IAA obtained

Question 9 asks if the height is reported in the medical record

- Check the appropriate box. If the answer is “**Yes**,” complete the following for the information measured *closest* to the date of diabetes diagnosis:
 - Question 9a - record the participant’s height and identify if that height is in centimeters or inches, and
 - Question 9b - record the date the height was measured.

Question 10 asks if the weight is reported in the chart

- Check the appropriate box. If the answer is “**Yes**,” complete the following for the weight measured *closest to the date of diabetes diagnosis*:
 - Question 10a - record the participant’s weight and identify if that weight is in kilograms or pounds, and
 - Question 10b - record the date the weight was measured.

Question 11 asks if insulin was ever used (*the window is from diagnosis to 6 months post diagnosis*)

- Check the appropriate box.
- If the answer is “**Yes**” complete:
 - 11a - the date insulin was begun.

If there is no information in the medical record on insulin use, check the ‘no information’ box.

Question 12 asks if insulin was ever discontinued

- Check the appropriate box. If the answer is “**Yes**” complete:

- 12a - the date insulin was stopped, and
- 12b - did DKA occur while off insulin?, and
- 12c - was insulin restarted? If the answer is “Yes,” record
 - 12c(1) - the date insulin was restarted

If there is no information in the medical record on insulin use, check the ‘no information’ box.

Question 13 asks if the participant has acanthosis nigricans

- Check the appropriate box.
- If there is no information in the medical record on acanthosis nigricans, check the ‘no information’ box.

Question 14 asks if DKA was noted in the medical record (*the window is from diagnosis to 6 months post diagnosis*)

- Check the appropriate box. If yes, complete the detail related to DKA as noted in the medical record.
- If there is no information in the medical record on DKA, check the ‘no information’ box.

10.4. EXTENDED CORE FORM CODES FOR COMPLETION

SEARCH Codes for conditions* listed by providers in the diabetes type “other_specify” field and Drug Code List (11.28.12). Please see Section 11 Appendix A for a complete version of the Technical Report on Algorithms for additional information.

Note: this list does not change which participants are eligible for in person clinic visits. Over the history of SEARCH, we have not seen youth with ‘secondary’ diabetes, but we have seen MODY, permanent neonatal, and “other and unknown” types. The table below uses the codes to indicate who is and is not eligible for an in person visit.

ELIGIBLE for in person visit	NOT ELIGIBLE for in person visit
<p>Type 1 (all subtypes)</p> <p>Type 2</p> <p>MODY (all category 3 - Genetic defects of beta-cell function)</p> <p>Permanent neonatal diabetes</p> <ul style="list-style-type: none"> • 1012 Permanent neonatal due to Kir 6.2 mutation • 1013 Permanent neonatal due to SUR mutation • 1014 Permanent neonatal due to INS (insulin gene mutations) • 1088 Permanent neonatal type not specified <p>All category 12 (Type unknown)</p>	<p>Category 4 - Genetic defects in insulin action</p> <p>Category 5 - Exocrine pancreatic</p> <p>Category 6 - Endocrinopathies</p> <p>Category 7 - Drug/chemical induced</p> <p>Category 8 - Infections</p> <p>Category 9 - Other known types</p> <p>Category 10 (except codes shown on left)</p> <p>Category 11 (Gestational diabetes)</p>

Category	Things to code in category
Other specific types	
1. Type 1, T1A Immune mediated; T1B Idiopathic; IDDM	<ul style="list-style-type: none"> • Are already coded on the form and do not require additional codes
2. Type 2 NIDDM; Insulin resistant DM (no other type mentioned)	<ul style="list-style-type: none"> • Are already coded on the form and do not require additional codes
3. Genetic defects of beta-cell function	<ul style="list-style-type: none"> • 300 MODY, type not specified, or specific MODY types as below: • 301 MODY 1, HNF4a • 302 MODY 2, GCK, glucokinase • 303 MODY 3, HNF1a • 304 MODY 4 • 305 MODY 5 • 306 MODY 6 • 307 MODY 7 • 308 MODY 8 • 309 MODY 9 • 310 MODY 10 • 311 MODY 11 • 312 MODY 12 • 320 mitochondrial DNA • 399 other, type not specified
4. Genetic defects in insulin action	<ul style="list-style-type: none"> • 401 Leprechaunism • 402 Lipoatrophic diabetes • 403 Rabson-Mendenhall syndrome • 404 Type A insulin resistance • 499 other, type not specified
5. Exocrine pancreatic	<ul style="list-style-type: none"> • 501 cancer, neoplasia NOTE: if said to be secondary to cancer <u>medicine</u> – code as #7, not here • 502 cystic fibrosis • 503 fibrocalculus • 504 hemochromatosis • 505 pancreatitis • 506 trauma/pancreatectomy • 599 other, type not specified
6. Endocrinopathies	<ul style="list-style-type: none"> • 601 acromegaly • 602 alderosteroma • 603 Cushing's syndrome • 604 glucagonoma • 605 hyperthyroidism • 606 somatostatinoma • 699 other, type not specified

7. Drug/chemical induced	<ul style="list-style-type: none"> • 701 beta-adrenergic agonists (see list) • 702 diazoxide • 703 dilantin (phenytoin-seizure medicine) • 704 gamma-interferon • 705 glucocorticoids/steroids (see list) • 706 thyroid hormone • 707 thiazides (see list) • 708 pentamidine • 709 nicotinic acid • 710 Vacor • 711 Antipsychotics and atypical antipsychotics (see list) • 799 other, type not specified • NOTE: if said to be secondary to cancer <u>medicine</u> – code here, not #5
8. Infections	<ul style="list-style-type: none"> • 801 congenital rubella • 802 cytomegalovirus • 899 other infections, type not specified
9. Other known types	<ul style="list-style-type: none"> • 901 “stiff-man” syndrome • 902 anti-insulin receptor antibodies • 999 other
10. Genetic syndromes	<ul style="list-style-type: none"> • 1001 Down • 1002 Friedreich Ataxia • 1003 Huntington chorea • 1004 Klinefelter • 1005 Laurence-Mood-Biedel syndrome • 1006 myotonic dystrophy • 1007 Turner • 1008 Wolfram • 1009 porphyria • 1010 Prader-Willi syndrome • 1011 other named syndromes • 1012 <u>Permanent neonatal</u> due to Kir 6.2 mutation • 1013 Permanent neonatal due to SUR mutation • 1014 Permanent neonatal due to INS (insulin gene mutations) • 1088 Permanent neonatal type not specified • NOTE: If <u>transient neonatal only: not eligible, unregister</u> • 1098 other genetic syndrome, type not specified • 1099 secondary, type not specified
11. Gestational diabetes (<u>not eligible</u>)	<ul style="list-style-type: none"> • 1101 GDM, gestational DM

<p>12. Type unknown</p>	<ul style="list-style-type: none"> • 1299 FOR ALL • unknown • comments about being uncertain of type • hybrid • Diabetes Mellitus, type not specified • Diabetes Mellitus, type not specified • DM, Type 1 vs. Type 1B and 2 • type 1 ½, or 1.5; • still determining • Insulin dependent diabetes mellitus and Type II (i.e. both types mentioned) • new onset diabetes, type not specified • Impaired glucose tolerance • NOTE: if glucose intolerance <u>only</u>: not eligible, unregister • Insulin resistance • NOTE: if insulin resistance <u>only</u>: not eligible, unregister • other comments without clear statement of type
<p>Other issues</p>	<ul style="list-style-type: none"> • If field says: doesn't have DM, or never diagnosed: <u>unregister</u> • If case has notes that are not included in this list: contact CoC for decision about how to query clinical record or which code to use. • CoC refers such cases to ROC for review and decision on regular basis.
<p>*From: American Diabetes Association: Diagnosis and Classification of Diabetes Mellitus. Diab Care 35:S64-S71, 2012</p>	

Drug Code Listing

Beta₂-adrenergic agonists (Code 701)

Generic name [followed by common brand names, if specific drug is listed]

Short acting

- Albuterol (salbutamol) [AccuNeb; ProAir HFA; Proventil HFA; Ventolin HFA; VoSpire ER],
- Levalbuterol [Xopenex HFA; Xopenex]
- Metaproterenol [Apo-Orciprenaline; ratio-Orciprenaline; Tanta-Orciprenaline]
- Terbutaline

Long acting

- Salmeterol [Serevent Diskus]
- Formoterol [Foradil Aerolizer; Perforomist]
- Arformoterol [Brovana]

Glucocorticoids/steroids (Code 705)

Generic name [followed by common brand names, if specific drug is listed]

- Betamethasone [Celestone; Celestone Soluspan; Diprolene; Diprolene AF; Luxiq]
- Budesonide [Entocort EC; Pulmicort Flexhaler; Pulmicort Respules]
- Corticotropin [H.P. Acthar]
- Cortisone [generic]
- Dexamethasone [Baycadron; Decadron, Dexamethasone Intensol; DexPak 10 Day TaperPak; DexPak 13 Day TaperPak; DexPak 6 Day TaperPak]
- Fludrocortisone [Florinef]
- Hydrocortisone [A-Hydrocort; Cortef; Solu-CORTEF]
- Methylprednisolone [A-Methapred; Depo-Medrol; Medrol; Medrol Dosepak; Solu-MEDROL]
- Prednisolone [Flo-Pred; Millipred; Millipred DP; Orapred ODT; Orapred; Pediapred; Veripred 20]
- Prednisone [PredniSONE Intensol]
- Triamcinolone [Aristospan; Kenalog-10; Kenalog-40]

Thiazides (Code 707)

The common generic names are:

- Hydrochlorothiazide
- Bendroflumethiazide
- Chlorothiazide
- Methyclothiazide

By brand name- many combination drugs have a thiazide as one of several ingredients. This list is to help if a specific drug is listed).

- Accuretic Tablets: (hydrochlorothiazide, quinapril hydrochloride)
- Aldactazide Tablets: (hydrochlorothiazide, spironolactone)

- Amiloride Hydrochloride and Hydrochlorothiazide Tablets: (amiloride hydrochloride, hydrochlorothiazide)
- Amturnide Tablets: (aliskiren, amlodipine, hydrochlorothiazide)
- Atacand HCT 16-12.5 Tablets: (candesartan cilexetil, hydrochlorothiazide)
- Atacand HCT 32-12.5 Tablets: (candesartan cilexetil, hydrochlorothiazide)
- Avalide Tablets: (hydrochlorothiazide, irbesartan)
- Benicar HCT Tablets: (hydrochlorothiazide, olmesartan medoxomil)
- Capozide 25/15 Tablets: (captopril, hydrochlorothiazide)
- Capozide 25/25 Tablets: (captopril, hydrochlorothiazide)
- Capozide 50/15 Tablets: (captopril, hydrochlorothiazide)
- Capozide 50/25 Tablets: (captopril, hydrochlorothiazide)
- Chlorothiazide Tablets, USP: (chlorothiazide)
- Corzide Tablets: (bendroflumethiazide, nadolol)
- Diovan HCT Tablets: (hydrochlorothiazide, valsartan)
- Diuril Oral Suspension: (chlorothiazide)
- Dyazide Capsules: (hydrochlorothiazide, triamterene)
- Enalapril Maleate and Hydrochlorothiazide Tablets, USP: (enalapril maleate, hydrochlorothiazide)
- Exforge HCT Tablets: (amlodipine, hydrochlorothiazide, valsartan)
- Fosinopril Sodium and Hydrochlorothiazide Tablets, USP: (fosinopril sodium, hydrochlorothiazide)
- Hydrochlorothiazide Capsules: (hydrochlorothiazide)
- Hydrochlorothiazide Tablets, USP: (hydrochlorothiazide)
- Hyzaar 100-12.5 Tablets: (hydrochlorothiazide, losartan potassium)
- Hyzaar 100-25 Tablets: (hydrochlorothiazide, losartan potassium)
- Hyzaar 50-12.5 Tablets: (hydrochlorothiazide, losartan potassium)
- Intravenous Sodium Diuril: (chlorothiazide sodium)
- Lopressor HCT 100/25 Tablets: (hydrochlorothiazide, metoprolol tartrate)
- Lopressor HCT 50/25 Tablets: (hydrochlorothiazide, metoprolol tartrate)
- Lotensin HCT Tablets: (benazepril hydrochloride, hydrochlorothiazide)
- Maxzide Tablets: (hydrochlorothiazide, triamterene)
- Maxzide-25 mg Tablets: (hydrochlorothiazide, triamterene)
- Methyclothiazide Tablets, USP: (methyclothiazide)
- Methyldopa and Hydrochlorothiazide Tablets, USP: (hydrochlorothiazide, methyldopa)
- Metoprolol Tartrate and Hydrochlorothiazide Tablets: (hydrochlorothiazide, metoprolol tartrate)
- Micardis HCT Tablets: (hydrochlorothiazide, telmisartan)
- Microzide Capsules: (hydrochlorothiazide)
- Prinzide Tablets: (hydrochlorothiazide, lisinopril)
- Propranolol Hydrochloride and Hydrochlorothiazide Tablets: (hydrochlorothiazide, propranolol hydrochloride)
- Tekturna HCT Tablets: (aliskiren, hydrochlorothiazide)
- Teveten HCT Tablets: (eprosartan mesylate, hydrochlorothiazide)
- Tribenzor Tablets: (amlodipine, hydrochlorothiazide, olmesartan medoxomil)

- Uniretic Tablets: (hydrochlorothiazide, moexipril hydrochloride)
- Vaseretic Tablets: (enalapril maleate, hydrochlorothiazide)
- Zestoretic 10-12.5 Tablets: (hydrochlorothiazide, lisinopril)
- Zestoretic 20-12.5 Tablets: (hydrochlorothiazide, lisinopril)
- Zestoretic 20-25 Tablets: (hydrochlorothiazide, lisinopril)
- Ziac Tablets: (bisoprolol fumarate, hydrochlorothiazide)

Antipsychotics and atypical antipsychotics (Code 711). Generic name is followed by brand name, then brand name sort

Sorted by generic name

Generic name	Brand name
• Amisulpride	• Solian
• Aripiprazole	• Abilify
• Asenapine	• Saphris
• Chlorpromazine	• Thorazine
• Chlorpromazine	• Largactil
• Chlorprothixene	• Cloxan
• Chlorprothixene	• Taractan
• Chlorprothixene	• Truxal
• Clopenthixol	• Sordinol
• Clozapine	• Clozaril
• Cyamemazine	• Tercian
• Droperidol	• Droleptan
• Droperidol	• Inapsine
• Flupenthixol	• Depixol
• Flupenthixol	• Fluanxol
• Fluphenazine	• Prolixin
• Haloperidol	• Haldol
• Haloperidol	• Serenace
• Iloperidone	• Fanapt
• Levomepromazine	• Nozinan
• Lurasidone	• Latuda
• Mesoridazine	• Serentil
• Olanzapine	• Zyprexa
• Paliperidone	• Invega
• Periciazine	• Periciazine
• Perphenazine	• Trilafon
• Pimozide	• Orap
• Prochlorperazine	• Compazine
• Promazine	• Promazine

- Promethazine
- Quetiapine
- Risperidone
- Sertindole
- Thioridazine
- Thiothixene
- Trifluoperazine
- Triflupromazine
- Ziprasidone
- Zotepine
- Zotepine
- Zotepine
- Zotepine
- Zuclopenthixol
- Zuclopenthixol
- Zuclopenthixol
- Phenergan
- Seroquel
- Risperdal
- Serdolect
- Mellaril
- Navane
- Stelazine
- Vesprin
- Geodon
- Nipolept
- Losizopilon
- Lodopin
- Setous
- Cisordinol
- Clopixol
- Acuphase

Sorted by brand name

Generic name	Brand name
• Aripiprazole	• Abilify
• Zuclopenthixol	• Acuphase
• Zuclopenthixol	• Cisordinol
• Zuclopenthixol	• Clopixol
• Chlorprothixene	• Cloxan
• Clozapine	• Clozaril
• Prochlorperazine	• Compazine
• Flupenthixol	• Depixol
• Droperidol	• Droleptan
• Iloperidone	• Fanapt
• Flupenthixol	• Fluanxol
• Ziprasidone	• Geodon
• Haloperidol	• Haldol
• Droperidol	• Inapsine
• Paliperidone	• Invega
• Chlorpromazine	• Largactil
• Lurasidone	• Latuda
• Zotepine	• Lodopin
• Zotepine	• Losizopilon
• Thioridazine	• Mellaril
• Thiothixene	• Navane

*SEARCH for Diabetes in Youth
Manual of Procedures*

- Zotepine
- Levomepromazine
- Pimozide
- Periciazine
- Promethazine
- Fluphenazine
- Promazine
- Risperidone
- Asenapine
- Sertindole
- Haloperidol
- Mesoridazine
- Quetiapine
- Zotepine
- Amisulpride
- Clopenthixol
- Trifluoperazine
- Chlorprothixene
- Cyamemazine
- Chlorpromazine
- Perphenazine
- Chlorprothixene
- Triflupromazine
- Olanzapine
- Nipolept
- Nozinan
- Orap
- Periciazine
- Phenergan
- Prolixin
- Promazine
- Risperdal
- Saphris
- Serdolect
- Serenace
- Serentil
- Seroquel
- Setous
- Solian
- Sordinol
- Stelazine
- Taractan
- Tercian
- Thorazine
- Trilafon
- Truxal
- Vesprin
- Zyprexa

(2/13)

APPENDIX A: QUESTION & ANSWER FROM DECEMBER 2012 EXTENDED CORE TRAINING

Background to change in Question 7: What is the participant's diabetes type?

We had various sources for diabetes type and the other field was being used differently in the algorithm and none easily lined up with the ADA categories type. The Registry Oversight Committee came up with an approach to capture the most common types without any change.

The first 4 codes (Type 1 and Type 2) will capture ~95% of the case.

Instead of having a whole series of "other" the person reviewing the record will write down what it says in the record in the box. Then there will be a series of codes to allow us to apply a code to what was written. All the things that we used to call secondary, are going to show up under the box so will understand secondary to what. The list comes from the ADA classification committee and will be evolving. There will be times when you come across something that does not fit or you don't know where it fits. If you can't resolve it by talking to your PI, then send it to the CoC (Susan) that will take it to the ROC for a decision so that if it is to come up again, there will be consistency. Might end up evolving over time to add more codes as people find things that are hard to classify. Ken has set it up so that you can save the form, so if they have a question about you can speak to your PI or the CoC and upon receiving an answer you can go back in and modify the saved form to reflect the decision. At diagnosis the participant was a Type 1 and during the review post 6 month there is not a definitive diagnosis. If there is no additional type information in the chart at 6 months, then you copy over what was found at diagnosis, assuming you have not been able to find anything that it has changed. If at 4 months, you take it, but if there is nothing within the 6 months window then copy it over. IPS is not used in the hierarchy algorithm.

Coding sheet Overview:

On the left category are the ADA categories

On the right side there are the specific examples of things in the category where we know they exist.

If a staff member cannot discern code, send an email to the PI, CoC (Susan) or to the ROC committee.

Process of entering: if you put something in the other specified field, and do not put a code in, a query will be sent to you. Both the code and the word phrase have to be entered.

Code Box: do not need a leading zero you can put 0303 or 303. Do not put the category number. The first digit is the whole category. MODY, but no specification (300), if they give you a type, you can break it out. All other categories 99 code is to use for the other not specified code. The specific things that are listed are rare, but they are in the ADA classifications.

500: cancer of pancreas, 501, 505, 506, but if someone has leukemia, and diabetes developed due to the drug used and that would go under the 7. Cystic Fibrosis (CF) is another common one. Diabetes secondary to Cystic Fibrosis, coded under "other" 502. Provider said Type 1 with Cystic Fibrosis so would code Type 1 A and would not code Cystic Fibrosis. A few cases where the "other" case indicates in the specified field states "does not have diabetes", or "never diagnosed", in this case you would unregister them.

700: Could have been 705 (steroids), 799 (unspecified), 711 (antipsychotic medication). At the end of the code list you will see the drug code list and you can look up the drug (generic and brand name) ex: due to albuterol and look on list and see that it is 701.

800: Cushing syndrome, Congenital Rubella under 801.

1000: Most common is under 10, genetic syndromes (Downs); 1011 is for “other” named syndromes. Permanent neonatal diabetes 1012. Transient neonatal not eligible, do not code. Neonatal diabetes, verify the time that you find them that they are still diabetic and then code as permanent neonatal type not specified. Gestational diabetes, not eligible, do not register.

1200: Category 12, type unknown. 1299

Questions:

Form can be saved if you have questions and have to confirm an answer.

Are the sites going to get a query on the saved files? Currently do not send queries for saved forms. It will show up as “in process” in which there is a report.

Someone that has diabetes but also has hyperthyroidism, do not automatically attribute it is due to hyperthyroidism.

Type 1 secondary to CF; should code it as secondary.

An example of secondary due to medications:

- A semi-common cause is Kidney/Liver/Heart transplants as the medication that is taken for rejection often causes diabetes.

The new core form will be effective as of January 1, 2013. You will not be able to initiate a new data entry on the old version of the form. You can go back and make edit to previous data on the old form, but you cannot start entering new core form entry on the old version of the form - it will only be the new form.

(2/13)